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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,898	09/05/2003	Natalia Viktorovna Stoynova	US-100	6923

38108 7590 03/13/2006

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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/654,898	STOYNOVA ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is assigned to Dr. Kailash C. Srivastava, in Art Unit 1655. To aid in correlating any papers for this application (i.e., USSN 10/313,643), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

Claims Status

2. Claims 1-19 are pending.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. §121:

- Group I – Claims 1-3 drawn to an L-amino acid producing *Escherichia* organism with inactivated *mlc* gene, classified under Class 435, Subclass 71.2, for example
- Group II – Claims 4-5 drawn to a method to produce L-amino acid via culturing an *Escherichia* organism with inactivated *mlc* gene, classified under Class 435, Subclass 115, for example.
- Group III – Claims 7-9 drawn to an L-amino acid producing *Escherichia coli* having inactivated *mlc* gene, wherein said gene is deleted, classified under Class 435, Subclass 71.1, for example.
- Group IV – Claims 10-11 drawn to an L-amino acid producing *Escherichia coli* having inactivated *mlc* gene, wherein said gene is mutated, classified under Class 435, Subclass 440, for example.
- Group V – Claims 13 and 16-17 drawn to a method to produce L-amino acid via culturing an *Escherichia coli* with inactivated *mlc* gene, wherein the mlc gene has been deleted, classified under Class 435, Subclass 109, for example.
- Group VI – Claims 14-17 drawn to a method to produce L-amino acid via culturing an *Escherichia coli* with inactivated *mlc* gene, wherein the mlc gene, or expression of said gene been mutated, classified under Class 435, Subclass 115, for example.

- Group VII – Claim 18 drawn to an L-amino acid producing *Escherichia coli* having inactivated *mlc* gene, wherein said organism produces higher amounts of said L-amino acid than a wild type *Escherichia coli*, classified under Class 435, Subclass 41, for example.

- Group VIII – Claim 19 drawn to an L-amino acid producing *Escherichia coli* having inactivated *mlc* gene, wherein said organism produces higher amounts of said L-amino acid than a parent *Escherichia coli*, classified under Class 435, Subclass 6, for example.

Linking Claims

4. Claim 6 links inventions in Groups III-IV, while Claim 12 links inventions in Groups V-VI. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claims, identified above. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. §121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131- 32 (CCPA 1971). See also MPEP §804.01.

Inventions are Independent and Distinct

5. The inventions are distinct, each from the other because of the following reasons:

Invention in Group I is related to invention in Group II as product and process to make the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, for e.g., the method of invention in Group II to make a L-amino acid is applicable to make any L- amino acid via fermenting any microorganism with an inactive *mlc* gene. Similarly, said *Escherichia* organism may be applicable to produce amino acids other than L-threonine.

Inventions in Groups I, III-IV and VII-VIII are related to reach other as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, for e.g., the combination in Group I as claimed does not require the particulars of the subcombination as

claimed because it will still be applicable to produce an L-amino acid via fermentation regardless of the mechanism to inactivate the *mlc* gene. The required condition is that said gene is inactive and the organism is any organism in the Taxonomic Genus *Escherichia*. The subcombination has separate utility such as of producing an L-amino acid at a rate higher than that produced by an Escherichia coli having the intact/active *mlc* gene as long as the organism is an *Escherichia coli*, not any member of the Taxonomic Genus *Escherichia.*

Inventions in Groups I, III-IV and VII-VIII are related to inventions in Group II as product and process to make the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, any one of the products as long as it is a member of taxonomic Genus *Escherichia* and has an inactive *mlc* gene is applicable for the process in Group II to make the L-amino acid via fermentation because an *Escherichia* organism with inactive *mlc* gene is imperative to process.

Inventions in Groups I and II each are unrelated to inventions in each of Groups V-VI because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group I is directed to an organism of the taxonomic Genus *Escherichia* having a defective *mlc* gene and producing an L-amino acid. Said *Escherichia*, however, does not have to be *Escherichia coli.* The inventions in Groups V-VI method, nevertheless, require the microorganism to be an *Escherichia coli,* not merely an *Escherichia.* Furthermore, said *Escherichia coli* should have the *mlc* gene inactivated either by mutation or deletion. Therefore, the composition of Group I invention is not applicable for practicing method inventions in Groups V-VI and method II will not be practiced with method Groups V-VI because of it having different component/steps.

Invention in Group III is related to invention in Group V as product and process to make the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, for e.g., the method of invention in Group V to make a L-amino acid is applicable to make any L- amino acid via fermenting any *Escherichia coli* with an inactive *mlc* gene as long as said gene is rendered inactive via deletion. Similarly, said *Escherichia coli* organism may be applicable to produce amino acids other than L-threonine.

Invention in Group III is unrelated to inventions in Group VI because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group III is directed to a composition that produces an L-amino acid via a fermentation process, wherein the microorganism is an *Escherichia coli* having an inactive *mlc* gene, wherein said mlc gene is inactivated by deletion. Group VI invention, however, requires the *mlc gene* to be inactivated by mutation. Therefore, invention in Group III is not related to Group VI invention.

Invention in Group IV is unrelated to invention in Groups V because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group IV is directed to a composition that produces an L-amino acid via a fermentation process, wherein the microorganism is an *Escherichia coli* having an inactive *mlc* gene, wherein said *mlc* gene is inactivated by mutation. Group V invention, however, requires the *mlc gene* to be inactivated by deletion. Therefore, invention in Group IV is not related to Group V invention.

Invention in Group IV is related to invention in Group VI as product and process to make the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, for e.g., the method of invention in Group VI to make a L-amino acid is applicable to make any L- amino acid via fermenting any *Escherichia coli* with an inactive *mlc* gene as long as said gene is rendered inactive via mutation. Similarly, said *Escherichia coli* organism may be applicable to produce amino acids other than L-threonine.

Inventions in Groups VII and VIII are related to inventions in each of Groups II, V and VI as product and process to make the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, for e.g., the method of invention in II is applicable to make L- amino acid as long as the organism is an *Escherichia* with an inactive *mlc* gene. Invention in Group V to make a L-amino acid is applicable to make any L- amino acid via fermenting any *Escherichia coli* with an inactive

mlc gene as long as said gene is rendered inactive via deletion. Similarly, said *Escherichia coli* organism may be applicable to produce amino acids other than L-threonine. Same relationship exists between the inventions of Group VI and VIII or V and VIII.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive, particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (Class and subclass), and their recognized diverse subject matter, restriction for examination purposes as indicated is proper.

6. Applicants are advised that a reply to this requirement must include an identification of an invention elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of additional claims which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b). Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in

accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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March 2, 2006

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